K112860
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3 510(k) Summary

JUN - 8 2012

510(k) Owner/SUBMITTER	Coloplast A/S Holtedam 1 3050 Humlebaek - Denmark
CONTACT PERSON	Brian Schmidt Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA
DATE PREPARED	29 September 2011
CLASSIFICATION	Gastrointestinal tube & accessories 876.5980 Class II Enema kit 876.5210 Class I (Exempt)
COMMON NAME	Rectal Catheter and Accessories; Enema Kit
PROPRIETARY NAME	Peristeen™ Anal Irrigation
PREDICATE DEVICE	K083770, K103254
DEVICE DESCRIPTION	The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.
INDICATIONS	The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. Peristeen™ Anal Irrigation is a prescriptive device and should only be prescribed by a licensed physician. Peristeen™ Anal Irrigation has the same indications as the predicate device.
TESTING	The Peristeen rectal catheter has been subjected to biocompatibility and mechanical testing and is

	substantially equivalent to the predicate Peristeen device (K083770, K103254).
TECHNOLOGICAL CHARACTERISTICS	The Peristeen rectal catheter has the same intended use, general design, and fundamental scientific technology as the predicate Peristeen rectal catheter.
SUMMARY OF THE NONCLINICAL TESTS SUBMITTED	In vitro (bench) tests; flexibility, flow rate, balloon inflation, balloon peak pressure, burst diameter/volume, biocompatibility
SUMMARY OF CLINICAL TESTS SUBMITTED (AS APPLICABLE)	Not applicable
CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS	Substantial equivalence of the Peristeen Rectal Catheter is supported by a comparison of the design and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
% Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Corp
1601 West River Rd North
MINNEAPOLIS MN 55411

JUN - 8 2012

Re: K112860
Trade/Device Name: Peristeen™ Anal Irrigation System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 24, 2012
Received: May 25, 2012

Dear Mr. Schmidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2 Statement of Indications for Use

Indications for Use

510(k) Number (if known): K112860

Device Name: Peristeen™ Anal Irrigation System

Indications for Use:

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Prescription Use ___X___ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112860